

### **REMARKS**

Claims 1, 4, 6-7, 9-11, 13, 14, 19, 21, 23-26, 30, 32, 34-40, 56-65, 67, 68, 82, 103-112, 117-143, 145-147 and 149-158 are pending in this application with claims 14, 25, 26, 30, 34-40, 56-65, 67, 68 104-108, 111, 112, 117-143, 145-147 and 149-158 currently withdrawn from consideration. No amendments are made herein. Claims 2, 3, 5, 8, 12, 15-18, 20, 22, 27-29, 31, 33, 41-55, 66, 69-81, 83-102, 113-116, 144 and 148 were previously canceled. Accordingly, claims 1, 4, 6, 7, 9-11, 13, 19, 21, 23, 24, 32, 82, 103, 109 and 110 are currently before the Examiner. Accordingly, no new matter has been added.

### **Formal Matters**

Applicants acknowledge the Examiner's statement that, because no generic claims were found patentable, the claims remain restricted in scope to the elected species only (*see* Office Action at p. 2). Thus, the Examiner concluded that claims 14, 25, 26, 30, 34-40, 56-65, 67, 68, 104-108, 111, 112, 117-143, 145-147 and 149-158 are withdrawn from consideration as drawn to unelected species. *Id.* at p. 3.

### **35 U.S.C. §112**

Claims 1, 4, 6, 7, 9-11, 13, 19, 21, 23, 24 and 82 are rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for the asserted utility of the entire scope claimed. Specifically, the Examiner alleged that the field of antibiotic pharmaceutical development is highly unpredictable and that undue experimentation would be required to synthesize and screen the compounds within the current claim scope (*see* Office Action at pp. 5-6). Applicants note the Examiner's acknowledgement that the specification is enabling for the compounds tested, *i.e.*, those compounds shown in Table 2. *Id.* at p. 4.

With regard to undue experimentation, Chapter 2164.06 of the MPEP provides the following:

The quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195

USPQ 150, 153 (CCPA 1977). “The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.” (emphasis added) *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)).

Applicants submit that the specification provides reasonable guidance for one of ordinary skill to practice the claimed invention without undue experimentation. Specifically, Scheme 1 and Example 1 of the application as filed provide many general and specific methods for making the claimed compounds. These synthetic schemes provide a reasonable amount of guidance for one of ordinary skill to synthesize the claimed compounds. Further, Applicants have provided an assay for the measurement of antibacterial activity in Example 2 of the specification as filed. This assay provides a reasonable amount of guidance in the experimentation necessary to screen compounds and determine which tetracycline species are effective against many types of bacteria. Thus, the experimentation required by the pending claims is not undue.

Further, the Examiner stated that the scope of the invention encompasses “in excess of billions” of species (*see* Office Action at p. 5). Applicants submit that formula I encompasses a reasonable claim scope. Specifically,  $R^2$ ,  $R^2$ ,  $R^3$ ,  $R^8$ ,  $R^{10}$ ,  $R^{11}$  and  $R^{12}$  are each hydrogen; X is  $CR^6R^6$ ;  $R^4$  and  $R^4$  are each alkyl;  $R^5$  is hydrogen or hydroxyl;  $R^6$  and  $R^6$  are each hydrogen or alkyl; and at least one of  $R^7$  and  $R^9$  is not hydrogen. Thus, the scope of the claims is reasonable in view of the exemplified species and the description of the application as filed.

As a result, claims 1, 4, 6, 7, 9-11, 13, 19, 21, 23, 24 and 82 are enabled by the specification as filed. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

### **Claim Objections**

Claims 32, 103, 109 and 110 are objected to for being dependent upon a rejected base claim (*see* Office Action at p. 6). Applicants request reconsideration of the rejected base claim (*i.e.*, claim 1) as described *supra*. Applicants further request reconsideration of claims 32, 103, 109 and 110 upon a finding of patentability of the generic claims presented herein.

**CONCLUSION**

Applicants respectfully submit that this application is in condition for allowance. If there are any questions regarding this amendment and/or these remarks, the Examiner is respectfully requested to telephone the Applicants' attorney/agent undersigned.

Respectfully submitted,



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Date: June 24, 2010